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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Re: Appeal to the Board of Patent Appeals and Interferences

Serial I Filed:	No.:	ion of: Chet M. Crump, et al. 09/716,486 November 20, 2000 No.: 8937 Respiratory Suction Catheter Appar Improved Valve And Collar		Group Art Unit: 3743 Examiner: Joseph Fra Our Customer ID: 228 Our Account No.: 04- Attorney Ref.: BAL-6 (BA00	327 1403 6-CON-RCE	
1.	[]	NOTICE OF APPEAL: Pursuant to 37 CFR 1.191, Applicant hereby appeals to the Board of Appeals from the decision dated November 14, 2003 of the Examiner finally rejecting claims 1-12.				
2.	[X] <u>BRIEF</u> on appeal in this application pursuant to 37 CFR 1.192 is transmitted herewith in triplicate.				ed herewith in	
3.	[]	An <b>ORAL HEARING</b> is respectful after Examiner's Answer).	lly requested unc	ler 37 CFR 1.194 (due		
4.	[ ]	Reply Brief under 37 CFR 1.193(b)	) is transmitted he	erewith in triplicate	RECEIVE	
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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: Chet M. Crump, et al.

Serial No.: 09/716,486

Confirmation No.: 8937

Filed: November 20, 2000

Title: Respiratory Suction Catheter Apparatus
With Improved Valve and Collar

Examiner: Joseph Weiss, Jr.

Group Art Unit: 3743

Our Customer No.: 22827

### **APPEAL BRIEF**

Honorable Commissioner of Patents and Trademarks PO Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Applicants' hereby submit this Appeal Brief in accordance with 37 CFR §1.192 for the above-captioned application. The Notice of Appeal was filed on December 22, 2003, in accordance with 37 CFR §1.8.

Applicants are submitting the fee for the filing of the preset Appeal Brief as set forth in 37 CFR §1.17(c).

If any further fee or extension of time is required to obtain entry of the Appeal Brief, Applicants hereby petition the Commissioner to grant any necessary time extension, and the undersigned hereby authorizes the Commissioner to pay from Deposit Account No. 04-1403, any such fee not submitted herewith.

02/06/2004 CNGUYEN 00000012 09716486

### 1. REAL PARTY IN INTEREST:

By assignment recorded on November 30, 1998, at reel 9628, frame 0566, the real party in interest is BALLARD MEDICAL PRODUCTS, a company whose address is 12050 South Lone Peak Parkway, Draper, Utah, 84020.

### 2. RELATED APPEALS AND INTERFERENCES:

There are no related appeals or interferences.

### 3. STATUS OF CLAIMS:

The application was filed on November 20, 2000 with claims 1-12. Claims 1 and 10 were filed as independent claims.

By amendment that was mailed on August 30, 2002, claims 1 and 10 were amended.

By amendment that was mailed January 6, 2003, claims 1 and 10 were amended.

In a Request for Continued Examination (RCE) that was mailed on February 20, 2003, claims 1 and 10 were amended.

The claims (1 through 12) as amended as of February 20, 2003 are included in the attached Appendix.

Claims 1-7, 10 and 11 stand finally rejected (Paper No. 16 mailed on August 26, 2003), under 35 U.S.C. §103(a) as being unpatentable over Niermann, et al. (U.S. Patent Number 5,354,267) in view of Russo (U.S. Patent Number 5,775,325).

Claim 8 stands finally rejected (Paper Number 16, mailed on August 26, 2003) under 35 U.S.C. §103(a) as being unpatentable over <u>Niermann</u> and <u>Russo</u> and further in view of <u>Reynolds</u> (U.S. Patent Number 5,370,610).

Claim 9 stands finally rejected (Paper No. 16, mailed on August 26, 2003) under 35 U.S.C. §103(a) as being unpatentable over Niermann, Russo, Reynolds and further in view of Loescher, et al. (U.S. Patent Number 5,005,568).

Claim 12 stands finally rejected (Paper No. 16, mailed on August 26, 2003) under 35 U.S.C. §103(a) as being unpatentable over Niermann, and Russo, in view of Reynolds.

### 4. STATUS OF AMENDMENTS:

A final rejection was mailed on October 21, 2002 (Paper No. 8) and Applicants filed a Request for Continued Examination (RCE) on February 20, 2003 and amended claims 1 and 10.

Another Final Rejection was mailed on August 26, 2003 (Paper No. 16) rejecting all of the pending claims. Applicants mailed a Response on October 23, 2003 that traversed the rejections to the pending claims. Applicants' response was entered into the case by way of an Advisory Action mailed November 14, 2003 (Paper No. 18), but the final rejection to claims 1-12 was maintained.

### 5. SUMMARY OF THE INVENTION:

The invention relates to a respiratory suction apparatus that is used for removing secretions that build up in the lungs of a patient breathing with the assistance of a mechanical ventilator.

Claims 1-12 are drawn generally to a respiratory suction apparatus that has a suction catheter (Ref. No. 208 in the drawings 3A-3D) with a distal end (Ref. No. 208a in Fig. 3A) insertable into a respiratory tract of a patient for the removal of fluids. Negative pressure is applied to the suction catheter in order to remove the fluids. A protective sleeve (Ref. No. 120 in Fig. 2) surrounds a proximal longitudinal portion of the catheter and is present in order to reduce contamination.

A distal adaptor (Ref. No. 222 in Fig. 3A) is present and is configured for communication with a manifold (Ref. No. 200 in Fig. 3A) of the patient's artificial airway. A collar (Ref. No. 224a in Figs. 3A-3E) is disposed within the adaptor and will partially surround the distal end of the catheter when the catheter is withdrawn from the manifold. The collar and the catheter define a substantially uniform cylindrical space around the distal portion of the catheter. The cylindrical space is capable of directing lavage solution into the adaptor (specification at page 17, lines 10-14). A valve device (Ref. No. 232 in Figs. 3A-3E) is present and isolates the catheter from the manifold upon the withdrawal of the distal portion of the catheter from the manifold and the application of suction through the lumen of the catheter. The valve device is opened by advancement of the suction catheter through the valve device.

A lavage port (Ref. No. 228 in Fig. 3A) is in fluid communication with the cylindrical space that is defined by the collar and the catheter. The lavage port is in fluid communication with the patient's artificial airway through the cylindrical space and the adaptor (specification at page 17, lines 10-14).

### 6. <u>ISSUES:</u>

Are claims 1-12 obvious under 35 U.S.C. §103(a) by Niermann, et al. (U.S. Patent No. 5,354,267) in view of Russo; Niermann and Russo in view of Reynolds (U.S. Patent No. 5,370,610); Niermann, Russo and Reynolds in view of Loescher et al. (U.S. Patent No. 5,005,668); and Niermann and Russo in view of Reynolds?

### 7. GROUPING OF CLAIMS:

Claims 1-12 rise or fall together.

### 8. <u>ARGUMENTS:</u>

Each of the rejected claims is drawn to an apparatus that includes a collar disposed within an adaptor and that defines with a catheter a substantially uniform cylindrical space around a distal portion of the catheter. The cylindrical space is capable of directing lavage solution into the adaptor.

Each rejected claim also calls for a lavage port that is in fluid communication with the cylindrical space that is defined by the collar and the catheter. The lavage port is in fluid communication with the patient's artificial airway through the cylindrical space and the adaptor.

Additional elements of the apparatus are also called for as can be seen upon examination of claims 1 and 10.

# A. THE FINAL REJECTION FAILS TO PROVIDE THE REQUIRED SUGGESTION OR MOTIVATION TO COMBINE THE NIERMANN AND RUSSO REFERENCES

The first of three criteria that must be met to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings. Manual of Patent Examining Procedure, 700-16 (7<sup>th</sup> ed. rev. July 1998). The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q. 2d 1430 (Fed. Cir. 1990). In the present case, not only do the references lack any suggestion of the desirability of combining the references with one another, the references in fact actually suggest the desirability of **NOT** combining the references with one another.

Russo is directed towards a two part closed tracheal suction system that is capable of maintaining positive end expiratory pressure (PEEP) when the two parts are connected to one another, and also when the two parts are disconnected from one another (see Russo at column 2, lines 49-53). In order to maintain PEEP when disconnected, as shown in Fig. 4 of Russo, the tracheal suction system is provided with a valve 27 that has very thick side walls 29, 30 that only open in response to manual depression of buttons 24 and 25 (see Russo at column 4, lines 35-36; and column 5, lines 50-55). Valve 27 is not opened when a suction catheter is pressed against the valve 27, but is only opened upon manual depression of the buttons 24, 25 by a user (see Russo at column 4, lines 37-43).

In stark contrast, manual depression of buttons on the exterior of the structure in <u>Niermann</u> is not needed to open the valve 74 (see <u>Niermann</u> at column 4, lines 40-50). Even if <u>Niermann</u> were configured to be a two-part device, PEEP would not be maintained by the valve 74 if the valve 74 was by itself relied on to maintain PEEP.

In this regard, <u>Russo</u> specifically teaches against use of the <u>Niermann</u> valve, as exemplified by the following language taken directly from <u>Russo</u> at column 4, lines 32-43:

...Unlike the prior art duck bill valves mounted internally within the front connector (Niermann et. al. U.S. Pat. No. 5,345,267) the present invention valve 27 has thick not easily deformed side walls 29 and 30 of around 0.080 inches.

Unlike Niermann et. al. U.S. Pat. No. 5,345,267 or Bodi U.S. Pat No. 4,351,328 neither the valve 27 nor its slit 28 can be opened by inserting a relatively soft suction catheter because the present invention uses thick side walls 29 and 30 made from firm 75 Shore A Durometer material to keep both valve 27 and side walls 29 and 30 in a normally biased closed position.

Quoting again directly from Russo at column 2, lines 26-31:

...The <u>Coles et. al.</u> patent does show an internal duckbill valve similar to <u>Niermann et. al.</u> U.S. Pat. No.5,354,267 but none of these prior art valves are manually deformable by the user's hand to enable ease of insertion or retraction of a catheter on its own.

Again quoting directly from Russo at column 1, line 66 to column 2, line 2:

...In effect this rotary valve acts fairly similar to the stopcock type arrangement of the <u>Niermann et. al.</u> U.S. Pat. No. 5,354,267 device which can also crimp the catheter when the valve is rotated.

Russo thus explicitly teaches to one skilled in the art that various features of Niermann, such as the stopcock valve 16, valve 74, the single piece design, and the

insertability of the catheter 18, are either disfavored or inferior to the closed tracheal suction system of <u>Russo</u>. With all due respect, the Examiner has pointed to nothing in either <u>Russo</u> or <u>Niermann</u> that suggests a desirability of combining these references, particularly in view of the fact that <u>Russo</u> **explicitly teaches** that <u>Niermann</u> is a disfavored, inferior device and urges against the exact combination proposed by the Examiner.

As such, the Examiner has failed to prove a suggestion or motivation to combine Russo and Niermann, and consequently the first of three required criteria for establishing *prima facie* obviousness has not been met.

B. EVEN IF <u>NIERMANN</u> AND <u>RUSSO</u> WERE PROPERLY COMBINED, THE RESULTING COMBINATION DOES NOT TEACH OR SUGGEST THE CLAIMED INVENTION.

Another of the three criteria that must be met to establish a *prima facie* case of obviousness is that the combination of references must teach or suggest all of the claim limitations of Applicants' claim. Manual of Patent Examining Procedure, 700-16 (7<sup>th</sup> ed. rev. July 1998). To establish *prima facie* obviousness of a claimed invention all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180, U.S.P.Q. 580 (CCPA 1974). In addition, all words in the claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

All of the independent claims in Applicants' application call for a lavage port to be in fluid communication with a cylindrical space defined by a collar and a catheter in which the lavage port is also in fluid communication with the patient's artificial

airway through the cylindrical space and the adaptor. These claim limitations are not found in the combination of <u>Niermann</u> and <u>Russo</u> even if <u>Niermann</u> and <u>Russo</u> were properly combined.

Niermann seeks to provide a new and improved irrigation and suction apparatus that may be used during ventilation of a patient (see Niermann at column 1, lines 5-7). Niermann discusses previous irrigation and suction apparatuses known in the art (see Niermann at column 1, lines 12-22):

These patents disclose irrigation and suction apparatus for use during patient ventilation wherein the irrigation fluid is introduced, or injected typically under some pressure, into the apparatus and is directed simultaneously to both the trachea and lungs of the patient and to the exterior, and/or internal lumen, of the suction catheter to wash the catheter and to remove or dislodge any materials such as secretions or mucous from the patient's lungs which may have become lodged in the internal lumen of the catheter or lodged in the suction holes at the catheter's tip.

Niermann further states that it is undesirable to have an irrigation and suction apparatus where irrigation fluid may be directed simultaneously to both the patient and the exterior of the catheter. In this regard, Niermann teaches that a better arrangement exists in having an irrigation and suction apparatus that is capable of directing irrigation fluid to the patient in a step completely isolated from directing irrigation fluid to both the patient and the exterior of the catheter (see Niermann at column 1, lines 23-30):

It is believed that it is more effective and therefore preferable for patient irrigation and catheter washing or flushing to introduce the irrigation fluid in one step of operation solely to the trachea and lungs of the patient and solely to the catheter in a second step of operation thereby assuring more positive flow of the irrigation fluid to the patient and catheter in separate steps of operation.

The entire disclosure of Niermann is therefore directed to providing an irrigation and suction apparatus that is capable of directing irrigation fluid solely to the patient, and then may be reconfigured so that irrigation fluid may be directed solely to the exterior of the catheter to clean the catheter (see Niermann at column 1, lines 38-43). Niermann states that it is undesirable to introduce irrigation fluid when the catheter is present because doing so would cause mucous on the exterior of the catheter to be flushed into the lungs of the patient (see Niermann at column 1, lines 42-45). Niermann therefore discloses an apparatus that provides irrigation fluid either solely to the catheter (see Figure 2 of Niermann) or solely to the patient (see Figure 3 of Niermann). In this regard Niermann explicitly teaches that it is disfavored to provide for an irrigation and suction apparatus that is configured for providing irrigation fluid to the patient while the irrigation is also capable of contacting the catheter. As stated, such a configuration is expressly described as being a problem that exists in the art that the disclosure of Niermann seeks to alleviate.

The Examiner states that the above-mentioned citations to <u>Niermann</u> should be given no support or weight when evaluating the reference because they are located in the background to the invention section of <u>Niermann</u> (see the second full paragraph on page 9 of Paper No. 16). First, other portions of <u>Niermann</u> clearly disclose an apparatus that provides irrigation fluid either solely to the catheter or solely to the patient (see <u>Niermann</u> at Figs. 2 and 3; and column 6 lines 38-43). Second, the full disclosure of the patent must be considered in its entirety when determining whether this patent may be combined with another or whether this patent teaches the subject matter of Applicants' claims. *Ashland Oil v Delta Resins* 

& Refactories, 776 F.2d 281, 303, 227 U.S.P.Q. 657(Fed. Cir. 1985). The background of the invention section is part of the specification of a patent and should thus be considered by the Examiner. 37 C.F.R. §1.77(b) (2003).

Turning now to Russo, this reference discloses in Figures 5 and 6 a flushing port assembly 38 that is in communication with a passage 34 while the suction catheter 44 is present in the passage 34. Cleaning of the suction catheter 44 takes place when lavage solution is administered through the flushing port assembly 38 (see Russo at column 5, lines 40-42). An entrance seal 22 contains the lavage solution to the passageway 34 and does not permit the lavage solution to enter the patient's airway (see Russo at column 5, lines 42 and 43).

In order to administer lavage solution to the patient, an administration port assembly 17 is employed through which lavage solution is directed through passageway 19 and into the patient's airway (See Figure 6 of Russo; and column 5, lines 26-31). The seal 22 prevents any lavage solution administered through the administration port assembly 17 from entering the passage 34 (see Russo at column 5, lines 37-40). Russo does not teach communication between the flushing port assembly 38 and the patient's artificial airway for the simple fact that if Russo did teach this communication, there would be no need for the administration port assembly 17.

As can be seen, <u>Russo</u> teaches a suction catheter where lavage solution is administered to the patient in complete isolation from the suction catheter 44.

Additionally, the suction catheter 44 is cleaned by lavage solution while completely isolated from the patient. Therefore both <u>Russo</u> and <u>Niermann</u> disclose suction catheter apparatuses where lavage solution is administered to the patient in

complete isolation from the suction catheter, and where lavage solution is administered to the suction catheter in complete isolation from the patient. Any combination of the two references would result in a device that functions so as to completely isolate the patient when lavage solution is applied to the suction catheter, and functions to isolate the catheter when lavage solution is administered to the patient.

Turning now to the present application, claim 1 calls for a respiratory suction apparatus that has a collar and a catheter that define a substantially uniform cylindrical space around a distal portion of the catheter. A lavage port is in fluid communication with the patient's artificial airway through the cylindrical space. As previously discussed, this structure is not present in the combination of Niermann and Russo. The combination of references explicitly teaches isolation of the patient's artificial airway when lavage solution is placed into communication with the catheter. As such, even if one skilled in the art were somehow motivated to combine both Russo and Niermann, the resulting apparatus would not be the respiratory suction apparatus disclosed in claim 1 of Applicants' application.

Also, it would not have been obvious to modify the combination of Niermann or Russo such that lavage solution is in communication with the artificial airway of the patient through a cylindrical space defined in part by the catheter, because such a configuration is explicitly stated as being undesirable in the references (see Niermann at column 1, lines 23-30; and Russo at column 5, lines 26-31 and Fig. 6). On pages 8-10 in Paper No. 16, the Examiner states that the Applicants have not pointed to claim language in the pending claims that is the feature of the claimed invention that is not taught in the prior art. Respectfully, however, on pages 6 and 7

of the Response mailed June 18, 2003, Applicants clearly pointed to claim language in claim 1 of Applicants' application that calls for an apparatus that has a collar and a catheter that define a substantially uniform cylindrical space around a distal portion of the catheter, where a lavage port is in fluid communication with the patient's artificial airway through the cylindrical space.

Contrary to the Examiner's assertion, this feature of Applicants' claims is not taught by the combination of Russo and Niermann. As mentioned, the combination of references both explicitly teach towards having the lavage port not be in fluid communication with the patient's artificial airway through a cylindrical space defined by a collar and a catheter. Claims 1 and 10 of Applicants' application call for a structure that is completely opposite from that taught in the combination of Niermann and Russo.

Even if <u>Russo</u> did teach communication of the lavage port and the patient's artificial airway through the cylindrical space, incorporation of this teaching into <u>Niermann</u> would not have been obvious to one skilled in the art because doing so would change the principle of operation of <u>Niermann</u> that seeks to provide lavage solution in separate steps solely to the patient and then solely to the catheter. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims of Applicants' application *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

# C. THE FINAL REJECTION RELIES ON HINDSIGHT FOR THE REQUIRED MOTIVATION TO COMBINE AND MODIFY THE NEIRMANN AND RUSSO REFERENCES

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991). Absent Applicants' disclosure, there is simply no motivation for one skilled in the art to combine Niermann and Russo in order to arrive at a respiratory suction apparatus that has a collar and a catheter that define a substantially uniform cylindrical space where a lavage port is in fluid communication with the patient's artificial airway through the cylindrical space. The Examiner has failed to identify any prior art where such a combination is suggested. The only place that the Examiner could have attained the combination of Niermann and Russo is through Applicants' own disclosure. It is impermissible to use Applicants' disclosure as an instruction manual in order to piece together various portions of the prior art so that Applicants' claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260, 1266, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992).

In making an obviousness determination, to give one of ordinary skill in the art knowledge of the invention, when no prior art references convey or suggest that knowledge, "is to fall victim to the insidious effect of a hindsight syndrome where that which only the inventor taught is used against the teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1533, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983).

The Examiner has not found the recited claim elements in the prior art, or found a proper suggestion or teaching to combine or modify the prior art to achieve the claimed invention. The Examiner's suggested motivation for combining the references ("to permit suction catheter adaptor cleaning and sanitation while the device is in use," see page 3 of paper number 13) is not suggested and is in fact explicitly stated as being disfavored upon a reading of the references. As such, a prima facie case of obviousness has not been made.

Therefore, Applicants respectfully submit that independent claims 1 and 10 are patentable over the cited references. If an independent claim is non-obvious under 35 U.S.C. §103(a), then any claim depending therefrom is non-obvious. In re-Fine, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). All of the depending claims in Applicants' invention depend directly or indirectly from one of the two previously mentioned independent claims that are non-obviousness under §103(a).

Applicants therefore respectfully submit that claims 1-12 are patentable under 35 U.S.C. §103(a) in view of the prior art.

Applicants respectfully submit that the final rejection of claims 1-12 should be reversed, and that these claims should be allowed to issue in a U.S. Patent.

Respectfully submitted,

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### **APPENDIX**

### **CLAIMS (AS AMENDED) INVOLVED IN APPEAL:**

1. A respiratory suction apparatus comprising:

a suction catheter for removing fluids from a respiratory tract of a patient by insertion of a distal end of the catheter into said respiratory tract and withdrawal of the distal end of the catheter through a portion of said tract while applying negative pressure to a lumen of the catheter;

a protective sleeve surrounding a proximal longitudinal portion of the catheter; a distal adapter configured for communication with a manifold of a patient's artificial airway;

a collar disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from the manifold, the collar and the catheter defining a substantially uniform cylindrical space around a distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter;

a valve device configured in the adapter to substantially isolate the catheter from the manifold upon withdrawing the distal portion of the suction catheter from said manifold and applying suction through the catheter lumen, said valve device being opened by advancement of said suction catheter through said valve device; and

a lavage port in fluid communication with the cylindrical space defined by the collar and the catheter, the lavage port in fluid communication with the patient's artificial airway through the cylindrical space and the adapter.

- 2. A respiratory suction apparatus according to Claim 1, wherein the valve device comprises a flap valve disposed distal to a distal end of the collar.
- 3. A respiratory suction apparatus according to Claim 2, wherein the flap valve seats against the distal end of the collar upon applying suction through the catheter lumen.
- 4. A respiratory suction apparatus according to Claim 2, wherein the flap valve seats against a distal end of the catheter upon applying suction through the catheter lumen.
- 5. A respiratory suction apparatus according to Claim 1, further comprising a cleaning enclosure defined within the adapter wherein the distal end of the catheter is exposed to cleaning liquids and turbulent airflow during a cleaning procedure.
- 6. A respiratory suction apparatus according to Claim 5, wherein the valve device is disposed distal to the collar and comprises an aperture therethrough for establishing the turbulent airflow.

- 7. A respiratory suction apparatus according to Claim 6, wherein the valve device is disposed so as to seat against a distal end of the collar.
- 8. A respiratory suction apparatus according to Claim 6, wherein the airflow is filtered ambient air metered through an opening defined through a wall of the cleaning enclosure.
- 9. A respiratory suction apparatus according to Claim 8, further comprising a valve disposed in the opening.
- 10. A respiratory suction apparatus comprising: an elongate suction catheter having a distal end; a protective sleeve surrounding a proximal portion of the catheter; a distal adapter configured for communication with a manifold of a patient's artificial airway;

a collar disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from said manifold, the collar and the catheter defining a substantially uniform cylindrical space around a distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter;

a cleaning enclosure defined within the adapter wherein the distal end of the catheter is exposed to cleaning liquids and turbulent airflow during a cleaning procedure;

means for providing a predetermined rate of airflow to the enclosure responsive to negative pressure within the catheter;

the catheter being protected at all serviceable times against environmental contamination by a combination of the sleeve, adapter and enclosure;

a valve device, comprising a flap and a hinge, configured in the adapter whereby the flap occludes the catheter responsive to a pressure differential between said manifold and the enclosure, the catheter opens the flap by manual insertion pressure of the catheter on the flap, and the hinge retains the flap; and

a lavage port in fluid communication with the cylindrical space defined by the collar and the catheter, the lavage port in fluid communication with the patient's artificial airway through the cylindrical space and the adapter.

- 11. A respiratory suction apparatus according to Claim 10, wherein the rate of airflow is responsive to application of negative pressure in the catheter.
- 12. A respiratory suction apparatus according to Claim 11, wherein the rate of airflow is filtered ambient air and the means for providing a predetermined rate of airflow further comprising an opening in the enclosure.